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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,527	02/05/2004	Michael Jon White	01467.US1	5399
25533	7590	01/24/2007	EXAMINER	
PHARMACIA & UPJOHN 7000 Portage Road KZO-300-104 KALAMAZOO, MI 49001			BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/24/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/772,527	WHITE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08),<br>Paper No(s)/Mail Date <u>5/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

**First Office Action on the Merits**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description, enablement and best mode for practicing the claimed invention.

The specification is objected to because the strain of *Fusarium culmorum*, i.e., *F. culmorum* UC 16069, used in the claimed process is a fungus that has not been deposited. Since the material is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the organism is not so obtainable or available, the requirement of 35 U.S.C. 112 may be satisfied by a deposit of the microorganism.

The specification does not disclose a repeatable process to obtain the microorganism nor is it apparent that the fungus is readily available to the public. It is noted that the applicants have not indicated that the organism has been deposited nor is there any indication in the specification as to public availability. If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strains have been deposited under the

Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and a receipt showing that the appropriate biological material was received and entered into the depository, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 applicants may provide assurance of compliance by an affidavit or declaration, or by statement by an attorney of record over his or her signature and registration number indicating that:

- a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time the deposit was made and that such test result indicated that said biological material was viable (see 37 C.F.R. 1.807); and,
- e) the deposit will be replaced if it should ever become inviable.

3. Claim 1-11 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

4. Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Fusarium culmorum* UC 16069, does not reasonably provide enablement for the entire genus of *Fusarium*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The claimed invention is a method for the production of a  $7\alpha,15\alpha$ -dihydroxylated derivative of DHEA utilizing a species of the genus *Fusarium* that is capable of said dihydroxylation.

The art teaches that not all species of the *Fusarium* genus or strains of *Fusarium culmorum* is capable of  $7\alpha,15\alpha$ -dihydroxylation of DHEA. For example, *F. graminearum* (DeFaye, 1978), *F. culmorum* (Kolek, 1999) and *F. moniliforme* (Kolek, 1999; US 6,930,192) have been shown to result in monohydroxylation of DHEA.

The present specification discloses dihydroxylation utilizing a specific strain of *F. culmorum*, *F. culmorum* UC 16069. However, it lacks guidance/direction to enable the skilled artisan to utilize other species and/or strains of said genus in the claimed process. Therefore, in order to practice the claimed invention commensurate in scope with these claims, the skilled artisan would have to test the ability of every species as well as every strain of Fusarium to obtain those capable of 7 $\alpha$ ,15 $\alpha$ -dihydroxylation of DHEA. Based on the state of the prior art, the unpredictability of the art in relation the activity of different species of Fusarium and the lack of guidance in the present specification, making said determination would result in undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for the following reasons:

- (a) claim 3 ends with a semicolon and not a period and, thus, the metes and bound of the claimed invention is unclear and
- (b) claim 5, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.  
See MPEP § 2173.05(d).

***Other Matters***

7. As stated above in #4, the present specification discloses *F. culmorum* UC 16069 is capable of dihydroxylation of DHEA. Therefore, it is suggested that the instant invention be limited to the utilization of said strain of *Fusarium*.

***Telephone Inquiry***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Radio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Barbara Radio*  
Barbara P. Radio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
January 19, 2007